

NOT FOR PUBLICATION

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

**IN RE HUMAN TISSUE PRODUCTS
LIABILITY LITIGATION**

Civ. No. 06-135
MDL No. 1763

THIS DOCUMENT RELATES TO:

**CYNDIA KENNEDY-MCINNIS, LEJUNE
KENNEDY, CAROLYN KENNEDY-GREEN,
ERNEST KENNEDY, BRANT KENNEDY,
DONNA MATTERN, ROBERT NENNO,
LAURIE STATHOPOULOS, JILL WIRTH,
VIRGINIA JACOBSON, ROLANN BAILEY,
SHAUNA CLAY and JOHN YEAGER on
behalf of themselves and all persons similarly
situated,**

Civ. No. 06-5140

OPINION

HON. WILLIAM J. MARTINI

Plaintiffs,

v.

**BIOMEDICAL TISSUE SERVICES, LTD.,
MICHAEL MASTROMARINO, SERENITY
HILL'S FUNERAL HOME, INC., THOMAS
E. BURGER FUNERAL HOME, INC.,
PROFETTA FUNERAL HOME,
REGENERATION TECHNOLOGIES, INC.,
LIFECCELL CORP., TUTOGEN MEDICAL,
INC., BLOOD & TISSUE CENTER OF
CENTRAL TX, and LOST MOUNTAIN
TISSUE BANK,**

Defendants.

MARTINI, U.S.D.J.

This is a putative class action brought by the relatives of decedents who claim that

the defendants harvested and processed bones and tissue from their relatives' bodies without proper consent.¹ Presently before the Court are motions for summary judgment filed by those defendants who processed the decedents' bones and tissue after they were harvested from the decedents' bodies. The plaintiffs oppose the motions and have filed their own cross-motion for summary judgment. For the following reasons, the motions for summary judgment filed by defendants Regeneration Technologies, Inc. ("RTI"), LifeCell Corp. ("LifeCell"), and Lost Mountain Tissue Bank ("Lost Mountain") are **DENIED**, and the plaintiffs' cross-motion for summary judgment is also **DENIED**.

BACKGROUND & PROCEDURAL HISTORY

The named representative plaintiffs in this class action are relatives of the following decedents: Lottie Ann Warren-Kennedy, Jean Guerinot, Ruth Passarella, Raymond Jacobson, Philip W. Bailey, and Albert Yeager. According to the named representative plaintiffs, each of the decedents' bodies went to one of three funeral homes located in New York State: Serenity Hill's Funeral Home, Inc., Thomas E. Burger Funeral Home, Inc., and Profetta Funeral Home. The plaintiffs claim that the funeral homes, after taking possession of the bodies, allowed Biomedical Tissue Services, Inc. ("BTS") to harvest (*i.e.*, remove) bones and tissue from the decedents for medical research and implantation. The plaintiffs allege that neither they nor the decedents consented to the harvesting of the body parts. Furthermore, the plaintiffs claim that the

¹ Criminal proceedings against certain of the defendants related to the alleged illegal harvesting of body parts are currently pending in state courts.

funeral homes never disclosed that such harvesting would occur.

The plaintiffs allege that the defendants' actions caused them severe emotional harm. Thus, they instituted this action on March 7, 2006 by filing a class action complaint in the Western District of New York. The purported class consists of "all next of kin relatives of decedents whose bodies were desecrated by BTS for the harvesting and sale of human body parts." (Am. Compl. ¶ 31.) The Judicial Panel on Multidistrict Litigation transferred the action to this Court for consolidation with *In re Human Tissue Products Liability Litigation*, MDL No. 1763. Then, on December 6, 2006, United States Magistrate Judge Ronald J. Hedges ordered the defendants in this action to answer or otherwise move in response to the plaintiffs' Amended Complaint.

In January 2007, defendants Blood and Tissue Center of Central Texas ("BTCCT"), LifeCell, Tutogen Medical, Inc. ("Tutogen"), RTI, and Lost Mountain (collectively, the "Tissue Bank Defendants") filed separate motions for summary judgment pursuant to Fed. R. Civ. P. 56. Each of these defendants is a tissue bank that allegedly received tissue and body parts from BTS. The plaintiffs contend that the Tissue Bank Defendants "failed to properly screen the body parts for proper authorizations, and upon information and belief, had knowledge that the body parts could have been obtained without consent." (Am. Compl. ¶ 34.)

The plaintiffs' Amended Complaint, while containing six counts, only names the Tissue Bank Defendants in two of the counts. In Count Two, the plaintiffs claim that the

Tissue Bank Defendants caused them great emotional pain and suffering by mishandling and desecrating their relatives' bodies. (Am. Compl. ¶¶ 98-101.) In Count Six, the plaintiffs assert that the Tissue Bank Defendants were negligent in failing to ensure that BTS obtained proper consents to harvest their relatives' body parts. (Am. Compl. ¶¶ 112-118.) The remaining counts of the Amended Complaint pertain to the other non-moving defendants.

Each of the Tissue Bank Defendants has moved for summary judgment on Counts Two and Six by relying on the New York Anatomical Gift Act, N.Y. Pub. Health Law §§ 4300-4309.² This act provides a good-faith defense to certain recipients of human tissue and immunizes them from liability. The plaintiffs oppose the Tissue Bank Defendants' motions and have cross-moved for summary judgment against the Tissue Bank Defendants, Thomas E. Burger Funeral Home, Inc., Profetta Funeral Home, and Serenity Hill's Funeral Home. In addition, the plaintiffs have moved for default judgment against defendants BTS and its Chief Executive Officer, Michael Mastromarino. The parties' motions are now before the Court.

STANDARD OF REVIEW

Summary judgment is appropriate when "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there

² Defendants Tutogen and BTCCT have additionally moved for summary judgment based on the plaintiffs' failure to establish standing. Those arguments are addressed in the Court's separate Opinion addressing BTCCT and Tutogen's summary judgment motions.

is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(c). The burden of showing that no genuine issue of material fact exists rests initially on the moving party. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). A litigant may discharge this burden by exposing “the absence of evidence to support the nonmoving party’s case.” *Id.* at 325. In evaluating a summary judgment motion, a court must view all evidence in the light most favorable to the nonmoving party. *See Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986); *Goodman v. Mead Johnson & Co.*, 534 F.2d 566, 573 (3d Cir. 1976).

Once the moving party has made a properly supported motion for summary judgment, the burden shifts to the nonmoving party to “set forth specific facts showing that there is a genuine issue for trial.” Fed. R. Civ. P. 56(e); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986). A party cannot simply rest on the allegations contained in his complaint in opposition to a properly supported summary judgment motion. Fed. R. Civ. P. 56 (providing that the party opposing summary judgment may not rest upon the mere allegations or denials of the pleading, but must, by affidavits or as otherwise provided in the rule, set forth specific facts showing that there is a genuine issue for trial).

If the non-moving party fails to sufficiently support its opposition by affidavits, depositions, answers to interrogatories, admissions on file, and pleadings, a court may

nevertheless deny or stay summary judgment if “it appear[s] from the affidavits of a party opposing the motion that the party cannot for reasons stated present by affidavit facts essential to justify the party’s opposition.” Fed. R. Civ. P. 56(f). A party moving pursuant to Rule 56(f), however, must submit an affidavit explaining “what particular information is sought; how, if uncovered, it would preclude summary judgment; and why it has not previously been obtained.” *Doe v. Abington Friends School*, 480 F.3d 252, 256 (3d Cir. 2007) (citations omitted). For purposes of Rule 56(f), a mere legal memorandum is insufficient, and failure to comply with Rule 56(f) in all, but the most exceptional cases, is “fatal to a claim of insufficient discovery on appeal.” *Bradley v. United States*, 299 F.3d 197, 207 (3d Cir. 2002); *see also Radich v. Goode*, 886 F.2d 1391, 1394 (3d Cir. 1989).

DISCUSSION

I. Tissue Bank Defendants’ Motions for Summary Judgment

In their summary judgment motions, LifeCell, RTI, and Lost Mountain³ argue that the facially valid consent forms supplied by BTS complied with the terms of the New York Anatomical Gift Act (the “Gift Act”), and therefore, the good-faith defense bars the

³ BTCCT and Tutogen also join in the motions for summary judgment on the issue of good faith immunity. However, as discussed in this Court’s separate Opinion addressing BTCCT and Tutogen’s summary judgment motions, all claims against BTCCT and Tutogen are dismissed for lack of standing.

plaintiffs' claims against the Tissue Bank Defendants.⁴ The Court, reserving judgment on the final determination of good faith, finds that summary judgment in favor of the Tissue Bank Defendants at this time would be premature without further discovery.

The Gift Act establishes the conditions and methods for executing an anatomical gift (*i.e.*, a donation of a body or body parts). It sets forth who may authorize an anatomical gift upon death, and the manner by which the decedent, or his (or her) next of kin, may consent to an anatomical gift. *See* N.Y. Pub. Health Law §§ 4300-4303. Additionally, the Gift Act protects donees of an anatomical gift, who act in good faith and in accordance with the statute, from civil suits and criminal prosecution related to receiving the gift. *See* N.Y. Pub. Health Law § 4306(3). Specifically, the statute states:

A person who acts in good faith in accord with the terms of this article or with the anatomical gift laws of another state is not liable for damages in any civil action or subject to prosecution in any criminal proceeding for his act.

Id.

Good-faith immunity under the Gift Act, however, is not absolute. Specifically, a donee is prohibited from accepting an anatomical gift under the following circumstances:

- (a) the donee has actual notice of contrary indication by the decedent;

⁴ Since the plaintiffs invoked diversity jurisdiction in this case, the Court must apply the law that the transferor court would have applied. *See* 17 JAMES WM. MOORE ET AL., MOORE'S FEDERAL PRACTICE ¶ 112.07 (3d ed. 1997 & Supp. 2007). Here, the Western District of New York would have applied New York law in assessing the validity of the donor consent forms and the applicability of a good-faith defense to liability.

- (b) where the donor has not properly executed an organ donor card, driver's license authorization to make an anatomical gift ... or otherwise given written authorization ... or has revoked any such authorization, and the gift is opposed by [the next of kin]; or
- (c) the donee has reason to believe that an anatomical gift is contrary to the decedent's religious or moral beliefs.

Id. § 4301(3).

Applying these provisions, one New York court held that a tissue bank that relies on facially valid documentation of consent provided by a third party is immune from suits brought by the decedent's kin. *See Nicoletta v. Rochester Eye & Human Parts Bank, Inc.*, 136 Misc. 2d 1065, 1069 (N.Y. Sup. Ct. 1987). In *Nicoletta*, the court granted summary judgment in favor of an eye bank in a suit brought by the decedent's father, who alleged physical and emotional injuries when he learned that his son's eyes were removed for donation based on consent provided by a woman claiming to be the decedent's wife. *Id.* Although the woman was not legally authorized to make the consent for donation because she was not, in fact, his legal wife, the court nonetheless granted summary judgment to the eye bank because "the Eye Bank removed the eyes of [the decedent] in justified reliance on the written permission form which was furnished by the Hospital." *Id.* The good-faith defense under the Gift Act shielded the *Nicoletta* eye bank from liability.

A determination of good faith is measured against an objective standard. *See id.*;

see also Carey v. New England Organ Bank, 446 Mass. 270, 282 (2006). As the court in *Nicoletta* noted:

[T]he legislature [in enacting the Gift Act] has created an objective standard by which the good faith of a donee could be measured. The Uniform Anatomical Gift Act establishes a statutory scheme which outlines the means of effecting an anatomical gift, the classes of individuals entitled to such gift, and the circumstances under which such a gift must be deemed null and void. None of the previous good-faith cases have involved such a definitive standard by which to judge a defendant's conduct.

Nicoletta, 136 Misc. 2d at 1069. Thus, unlike other contexts of good faith involving a determination of an individual's intent, the availability of the good-faith defense is an issue properly resolved by a Court on a motion for summary judgment. *See id.*; *see also Perry v. St. Francis Hosp. & Med. Ctr.*, 886 F. Supp. 1551, 1556-60 (D. Kan. 1995); *Lyon v. United States*, 843 F. Supp. 531, 533-34 (D. Minn. 1994).

In this case, the forms submitted by defendants LifeCell, RTI, and Lost Mountain appear to be facially valid consent forms under New York law.⁵ The consent forms submitted by LifeCell, RTI, and Lost Mountain are all identical. (Vento Aff; Hartill Aff.; Wade Aff.) Each is entitled "Biomedical Tissue Services Consent for Donation of

⁵ LifeCell submits consent forms for Lottie Ann Warren-Kennedy, Ruth Passarella, Raymond Jacobson, and Albert Yeager. (Vento Aff.) RTI submits consent forms for Lottie Ann Warren-Kennedy, Jean Guerinot, Ruth Passarella, Raymond Jacobson, and Albert Yeager. (Hartill Aff.) Lost Mountain submits consent forms for Lottie Ann Warren-Kennedy, Jean Guerinot, and Raymond Jacobson. (Wade Aff.)

Anatomical Gifts.” (*Id.*) In conformity with N.Y. Pub. Health Law § 4301(3), all of the forms state that a donor’s relative, “having no notice that this gift would have been opposed by the donor,” consents to the donation of specified tissues and/or bones. (*Id.*) In addition, each form contains a mark indicating that BTS obtained “Telephone Consent” to the anatomical gift from the decedent’s relative. (*Id.*) Such telephonic consent was in accordance with N.Y. Pub. Health Law § 4303(5), which allows an anatomical gift to be “made by his telegraphic, recorded telephonic, or other recorded message.” Although no telephonic audio recording was made for these consents, each of the forms were signed and dated by two witnesses in conformity with 10 N.Y. Comp. Codes R. & Regs. § 52-3.3(b) (allowing telephonic consent to an anatomical gift if it is “recorded or documented in writing by the tissue procurement service requesting the donation”). Therefore, the consents facially complied with the regulations implementing the Gift Act.⁶

The plaintiffs additionally argue that good-faith immunity is inapplicable in this case because the Tissue Bank Defendants knew or, at least, had constructive knowledge that the donor had not consented to the harvesting of tissue. (Am. Compl. ¶ 34.)

⁶ The plaintiffs also argue that the consents were invalid because LifeCell, RTI, and Lost Mountain did not confirm that the individual providing consent was of sound mind. (Pl.’s Opp. Br. at 9-14.) The Gift Act, however, does not require such confirmation. While the Gift Act provides that “[a]ny individual of sound mind and eighteen years of age or more may give all or any part of his body,” N.Y. Pub. Health Law § 4301(1), this provision refers to circumstances where the donor, during his or her lifetime, consents to an anatomical gift. Where the donor’s next of kin provides consent, the Gift Act contains no such “of sound mind” requirement. *See* N.Y. Pub. Health Law § 4301(2).

Evidence of such notice would negate the good-faith defense asserted by the Tissue Bank Defendants. *See Nicoletta*, 136 Misc. 2d at 1069 (granting summary judgment in favor of hospital because, *inter alia*, “[n]owhere in the pleadings or the transcripts of examinations before trial does it appear that the Eye Bank had actual notice that the gift was opposed by a member of any of the classes of individuals set forth in section 4301”); *see also Perry v. St. Francis Hosp. & Med. Ctr.*, 886 F. Supp. 1551, 1559 (D. Kan. 1995) (finding a material issue of fact regarding “actual notice of contrary indication” where plaintiffs submitted evidence that they “repeatedly expressed [to a hospital official] their opposition to removing [the decedent’s] eyes and bones”).

In support of their opposition to the defendants’ motions, the plaintiffs seek refuge in Fed. R. Civ. P. 56(f). Although the plaintiffs do not submit any evidence that the Tissue Bank Defendants knew of the relatives’ lack of consent, they have set forth in an affidavit that: (1) the Tissue Bank Defendants “had to or should have been aware” of BTS’ illegal activities; and (2) due to the stay of discovery in this case, information as to the knowledge of the Tissue Bank Defendants could not yet be provided. (White Affirmation ¶¶ 74-77.) The Tissue Bank Defendants deny this allegation both by way of legal memoranda and affidavits. They argue that they were not aware that consent, in fact, had not been obtained from the donors’ next of kin or that either the decedents or the decedents’ next of kin were in any way opposed to the donation.

Discovery has not commenced in this case on the issue of whether the Tissue Bank

Defendants were aware that the consent forms were fabricated or that there was contrary indication by the decedents or their next of kin. As these facts are essential in determining whether the Tissue Bank Defendants accepted an anatomical gift in violation of N.Y. Pub. Health Law § 4301(3) (prohibiting acceptance if the donee had notice that the decedent or their next of kin opposed such a gift), and whether the Tissue Bank Defendants are precluded from asserting good-faith immunity, the Court finds that a determination on the issue of good faith would be premature at this time. To accept the Tissue Bank Defendants' argument, that summary judgment could be granted based solely on the consent forms without examining whether the Tissue Bank Defendants knew that the consent forms were invalid, is to suggest that the Gift Act insulates potentially complicit tissue banks as long as they have received a completed consent form, even if there is evidence that the tissue banks knew, or had constructive knowledge, that the forms had been falsified. Such an interpretation would contravene the clear language of the Gift Act. Thus, the Court denies the motions for summary judgment brought by defendants LifeCell, RTI, and Lost Mountain.

II. Plaintiffs' Motion for Summary Judgment

In their opposition brief, the plaintiffs cross-move for summary judgment on various grounds. Specifically, they seek the entry of default judgment against defendants Michael Mastromarino and BTS, because they failed to answer the plaintiffs' Amended

Complaint.⁷ In addition, they seek entry of summary judgment against defendants Serenity Hill's Funeral Home, Inc., Thomas E. Burger Funeral Home, Inc., Profetta Funeral Home, and the Tissue Bank Defendants on various claims in the complaint.

The plaintiffs' cross-motion for summary judgment will be denied. In an order dated January 31, 2007, Magistrate Judge Hedges ordered that no motions shall be filed in this matter pending leave of the Court. The plaintiffs here did not request leave to submit their motion. Accordingly, the plaintiffs' motion will be dismissed without prejudice.

CONCLUSION

For the reasons stated above, RTI, Lifecell, and Lost Mountain's motions for summary judgment as well as Plaintiffs' cross-motion for summary judgment are **DENIED** at this time. An appropriate Order accompanies this Opinion.

s/William J. Martini
William J. Martini, U.S.D.J.

Dated: November 13, 2007

⁷ The Court notes that defendants Mastromarino and BTS have not yet filed a responsive pleading in any of the cases consolidated as *In re Human Tissue Products Liability Litigation*. Pursuant to this Court's order dated November 7, 2007, defendants Mastromarino and BTS may be subject to judgment by default if they do not file a responsive pleading before December 6, 2007. (Docket Entry No. 472.)